

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

_____)	
IN RE PHARMACEUTICAL INDUSTRY)	MDL No. 1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	Civil Action No.
_____)	01-CV-12257-PBS
)	
THIS DOCUMENT RELATES TO)	
)	Judge Patti B. Saris
<i>State of Montana v. Abbott Labs., Inc., et al..</i>)	
<i>02-CV-12084-PBS</i>)	
)	
<i>State of Nevada v. Abbott Labs., Inc., et al..</i>)	
D. Nev. Cause No. CV-12086-PBS (Nevada II))	
_____)	

**THE JOHNSON & JOHNSON DEFENDANTS'
INDIVIDUAL L.R. 56.1 STATEMENT OF UNDISPUTED FACTS**

Pursuant to Local Rule 56.1, Johnson & Johnson, Centocor, Inc., Janssen Pharmaceutica Products L.P., McNeil-PPC, Inc., and Ortho Biotech Products, L.P. (the “J&J Defendants”) identify the following material facts of record as to which there is no genuine issue to be tried..

1. Centocor, Inc., Janssen Pharmaceutica Products L.P, McNeil-PPC, Inc. and Ortho Biotech Products, L.P. are wholly-owned subsidiaries of Johnson & Johnson.¹

2. The drugs sold by the J&J Defendants that are alleged by Montana and Nevada to be subject to liability include Aciphex, Bicitra, Concerta, Ditropan XL, Duragesic, Elmiron, Erycette, Flexeril, Floxin, Grifulvin V, Haldol, Haldol Decanoate, Levaquin, Monistat-Derm, Mycelex, Neutraphos, Pancrease, Parafon Forte DSC, Polycitra, Procrit, Propulsid, Remicade, Regranex, Reminyl, Renova, Retin-A Micro, Risperdal, Spectrazole, Sporanox, Terazol, Tolectin, Topamax, Tylenol with codeine, Tylox, Ultracet, Ultram, Vascor, and Vermox.²

3. The difference between provider acquisition cost and AWP (“the spread”) for the drugs alleged by Montana and Nevada to be subject to liability was not greater than 30%.

- a. There is no record evidence that the spread on Aciphex was greater than 30%.
- b. There is no record evidence that the spread on Bicitra was greater than 30%.
- c. There is no record evidence that the spread on Concerta was greater than 30%.
- d. There is no record evidence that the spread on Ditropan XL was greater than 30%.
- e. There is no record evidence that the spread on Duragesic was greater than

¹ Schau Decl. Ex. 1 (State of Montana’s Second Amended Complaint (“Montana Complaint”), ¶¶ 83-87); Schau Decl. Ex. 2 (Nevada’s Amended Complaint (“Nevada Complaint”), ¶¶ 56-59).

² Schau Decl. Ex. 1 (Montana Complaint, Exhibit A); Schau Decl. Ex. 2 (Nevada Complaint, Exhibit A).

30%.

- f. There is no record evidence that the spread on Elmiron was greater than 30%.
- g. There is no record evidence that the spread on Erycette was greater than 30%.
- h. There is no record evidence that the spread on Flexeril was greater than 30%.
- i. There is no record evidence that the spread on Floxin was greater than 30%.
- j. There is no record evidence that the spread on Grifulvin V was greater than 30%.
- k. There is no record evidence that the spread on Haldol was greater than 30%.
- l. There is no record evidence that the spread on Haldol Decanoate was greater than 30%.
- m. There is no record evidence that the spread on Levaquin was greater than 30%.
- n. There is no record evidence that the spread on Monistat-Derm was greater than 30%.
- o. There is no record evidence that the spread on Mycelex was greater than 30%.
- p. There is no record evidence that the spread on Neutraphos was greater than 30%.
- q. There is no record evidence that the spread on Pancrease was greater than 30%.
- r. There is no record evidence that the spread on Parafone Forte DSC was greater than 30%.
- s. There is no record evidence that the spread on Polycitra was greater than 30%.
- t. There is no record evidence that the spread on Procrit was greater than 30%.
- u. There is no record evidence that the spread on Propulsid was greater than 30%.

- v. There is no record evidence that the spread on Remicade was greater than 32.1%.
- w. There is no record evidence that the spread on Regranex was greater than 30%.
- x. There is no record evidence that the spread on Reminyl was greater than 30%.
- y. There is no record evidence that the spread on Retin-A Micro was greater than 30%.
- z. There is no record evidence that the spread on Risperdal was greater than 30%.
- aa. There is no record evidence that the spread on Spectrazol was greater than 30%.
- bb. There is no record evidence that the spread on Sporanox was greater than 30%.
- cc. There is no record evidence that the spread on Terazol was greater than 30%.
- dd. There is no record evidence that the spread on Tolectin was greater than 30%.
- ee. There is no record evidence that the spread on Topamax was greater than 30%.
- ff. There is no record evidence that the spread on Tylenol with codeine was greater than 30%.
- gg. There is no record evidence that the spread on Tylox was greater than 30%.
- hh. There is no record evidence that the spread on Ultracet was greater than 30%.
- ii. There is no record evidence that the spread on Ultram was greater than 30%.
- jj. There is no record evidence that the spread on Vascor was greater than 30%.
- kk. There is no record evidence that the spread on Vermox was greater than 30%.
- 4. Plaintiffs' expert, Dr. Raymond S. Hartman, testified as follows:

Q. And what you do in Paragraph 21 [of your Liability and Damages Declaration] is you quote from the Court's August 2005 opinion in which the Court describes your methodology. And you say... "[The Court] concludes Hartman terms his overall approach the yardstick method because he intends to determine what the market reasonably expected the spread to be on average." Is that what you did in the class actions?

A. As for a yardstick for determination of liability, that's what I did, yes.

Q. And the yardstick that you used was 30 percent, correct?

A. That's correct.

Q. And that—you used that 30 percent yardstick because that's what you determined the market expectation to be, correct?

A. I used that 30 percent because I reviewed a set of comparator drugs. I reviewed a set of the—the information that is discussed in Paragraph 21, and I found the 30 percent to be a conservative bound for an expectation for a drug that was not subject to the—the exploitation of spread for spread competition or to move market share.

Q. And that expectation would apply to the Medicaid agencies as well as the rest of the marketplace, is that correct?

A. This expectation and this understanding was a—a general statement for the market as a whole.

Q. And that would include Medicaid, correct?

A. It—it includes all market participants.

Q. Including Medicaid, correct?

A. That's right.³

5. Through 2004, Nevada claims that it incurred "overcharge damages" with respect to Procrit of \$35,053.⁴

³ Schau Decl. Ex. 3 (Deposition of Raymond S. Hartman, August 22, 2006 Vol. 1, 31:9 – 32:21).

⁴ Schau Decl. Ex. 7 (Supplementary Declaration of Raymond S. Hartman ("Hartman Supp. Nevada Declaration"), June 20, 2006, Tables 1 and 4).

6. Through 2004, one or more of the J&J Defendants paid Nevada a total of \$267,568 in rebates with respect to Procrit.⁵

7. Nevada does not claim that it incurred “overcharge damages” with respect to Remicade, a drug sold by Centocor, Inc.⁶

8. Nevada has not submitted a claim for “overcharge damages” for any drug sold by any of the J&J Defendants other than Procrit.⁷

9. Through 2004, Montana claims that it incurred “overcharge damages” with respect to Procrit of \$72,814, comprised of \$49,464 in alleged damages for retail pharmacy reimbursements based on NDCs, and \$23,350 in alleged damages for physician-office reimbursements based on J-Code.⁸

10. Through 2004, one or more of the J&J Defendants paid Montana a total of \$146,474 in rebates with respect to Procrit.⁹

11. Through 2004, Montana claims that it incurred alleged “overcharge damages” with respect to Remicade of \$25,312, comprised of \$16,384 in alleged damages for retail pharmacy reimbursements based on NDCs, and \$8,928 in alleged damages for physician-office reimbursements based on J-Code.¹⁰

12. Through 2004, one or more of the J&J Defendants paid Montana a total of \$33,566 in Medicaid rebates with respect to Remicade.¹¹

13. Montana has not submitted a claim for “overcharge damages” for any drug sold by any of the J&J Defendants other than Procrit and Remicade.

⁵ Declaration of Jayson S. Dukes Regarding Nevada’s Claim (“Dukes Nev. Decl.”), ¶8.

⁶ Schau Decl. Ex. 7 (Hartman Supp. Nevada Declaration, Tables 1 and 4).

⁷ *Id.*

⁸ Schau Decl. Ex. 5 (Declaration of Raymond S. Hartman, June 13, 2006 (“Hartman Mont. Declaration”), Tables 1, 2 and 6).

⁹ Declaration of Jayson S. Dukes Regarding Montana’s Claim (“Dukes Mon. Decl.”), ¶8.

¹⁰ Schau Decl. Ex. 5 (Hartman Mont. Declaration, Tables 1, 2 and 6).

¹¹ Declaration of Jayson S. Dukes Regarding Montana’s Claim (“Dukes Mon. Decl.”), ¶10.

14. Montana's net reimbursement for Risperdal, inclusive of rebates, is less than Dr. Hartman's lower bound estimate of pharmacy acquisition cost.¹²

15. There is no record evidence that Montana's net reimbursement for Aciphex, Bicitra, Concerta, Ditropan XL, Duragesic, Elmiron, Erycette, Flexeril, Floxin, Grifulvin V, Haldol, Haldol Decanoate, Levaquin, Monistat-Derm, Mycelex, Neutraphos, Pancrease, Parafon Forte DSC, Polycitra, Procrit, Propulsid, Remicade, Regranex, Reminyl, Renova, Retin-A Micro, Risperdal, Spectrazole, Sporanox, Terazol, Tolectin, Topamax, Tylenol with codeine, Tylox, Ultracet, Ultram, Vascor, and Vermox, inclusive of rebates, was greater than Dr. Hartman's lower bound estimate of pharmacy acquisition cost.

16. There is no record evidence that Nevada's net reimbursement for Aciphex, Bicitra, Concerta, Ditropan XL, Duragesic, Elmiron, Erycette, Flexeril, Floxin, Grifulvin V, Haldol, Haldol Decanoate, Levaquin, Monistat-Derm, Mycelex, Neutraphos, Pancrease, Parafon Forte DSC, Polycitra, Procrit, Propulsid, Remicade, Regranex, Reminyl, Renova, Retin-A Micro, Risperdal, Spectrazole, Sporanox, Terazol, Tolectin, Topamax, Tylenol with codeine, Tylox, Ultracet, Ultram, Vascor, and Vermox, inclusive of rebates, was greater than Dr. Hartman's lower bound estimate of pharmacy acquisition cost.

17. Nevada Medicaid's reimbursement for Risperdal, after accounting for underpayment of dispensing costs, was lower than Walgreens' cost of acquiring and dispensing Risperdal.¹³

¹² Declaration of Eric M. Gaier, Ph.D., in Support of Defendants' Joint Motion for Summary Judgment in the States of Nevada and Montana, Feb. 8, 2007 ("Gaier Declaration"), ¶ 12 and Exhibit 3.

¹³ Gaier Declaration, ¶ 25 and Exhibit 9.

18. Nevada Medicaid's reimbursement for Levaquin, after accounting for underpayment of dispensing costs, was approximately the same as Walgreens' cost of acquiring and dispensing Levaquin.¹⁴

19. The ASPs for Procrit that Dr. Hartman used to calculate the "statute penalties" allegedly owed to Montana and Nevada for Procrit are lower than the ASPs for Procrit that Hartman calculated and submitted, under penalty of perjury, with his direct testimony in the Track 1 trial in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL 1456.

20. Had Dr. Hartman used the ASPs for Procrit that he submitted, under penalty of perjury, in his direct testimony in the Track 1 trial in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL 1456, the "overcharge damages" allegedly owed to Montana and Nevada for Procrit would have been \$77,443.

21. The ASPs for Remicade that Dr. Hartman used to calculate the "statute penalties" allegedly owed to Montana and Nevada for Remicade are lower than the ASPs for Remicade that Hartman calculated and submitted, under penalty of perjury, with his direct testimony in the Track 1 trial in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL 1456.

22. Had Dr. Hartman used the ASPs for Remicade that he submitted, under penalty of perjury, in his direct testimony in the Track 1 trial in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL 1456, the "overcharge damages" allegedly owed to Montana and Nevada for Remicade would have been \$20,487.

¹⁴ *Id.*

Dated: February 8, 2007

Respectfully submitted,

/s/ William F. Cavanaugh, Jr.

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Certificate of Service

I certify that a true and correct copy of the foregoing was served on all parties on February 8, 2007 via Lexis/Nexis File & Serve.

/s/ Andrew D. Schau

Andrew D. Schau